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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/047,745 | 01/15/2002 | James M. Campos | ROWE/03 | 5179 |
| 26875 | 7590 | 05/18/2005 | EXAMINER | |
| WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202 | | | SCHAETZLE, KENNEDY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/047,745 | Applicant(s) CAMPOS, JAMES M. | |
| | Examiner Kennedy Schaetzle | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29, 31-56, 58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-27, 29, 31-38, 40-56, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 9 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 6-8, 11, 14, 15, 19, 22-27, 31, 33, 35, 36, 38, 41-43, 47 and 49-56 rejected under 35 U.S.C. 102(b) as being anticipated by Kallok (Pat. No. 5,133,354).

Regarding claim 1 and claims with similar limitations, Kallok discloses a method of stimulating musculature comprising applying a resonant sequence of pulses (see Figs. 3 and 4, for example), spaced relative to one another such that each pulse subsequent to a first pulse in the sequence is effective to progressively stimulate and create tension in the musculature inwardly from the electrodes and towards the center of the musculature while maintaining the tension created in at least a portion of the musculature by each preceding pulse in the resonant sequence (note Fig. 1a-c and the text abridging cols. 2 and 3 wherein tension is cumulatively increased with each stimulation pulse). The examiner considers it inherent that the tension is created inwardly from the electrodes to the center of the musculature because stimulation resulting from the application of energy from an electrode naturally propagates outwardly from the source of stimulation such as shown in prior art Figs. 12A-C, with the difference between said prior art figures and the Kallok reference being that tension is maintained in the musculature with the Kallok pulsing system.

Regarding claims 2 and 3, since the applicant has not set forth the definition of a resonant sequence explicitly and with reasonable clarity, deliberateness and precision, one can arbitrarily consider pulse 80 (see Fig. 3) to be a first pulse and pulse 82 to be a second pulse of a resonant sequence. The first pulse has a frequency or spacing different from the second pulse.

Regarding claims 6 and 27, Kallok discloses the use of multiple sequences (note for example Fig. 4).

Regarding claims 7 and 8, a first sequence 98 has a different parameter than a second sequence 100 (note Fig. 4).

Regarding claim 11, the square wave pulse sequences shown in Fig. 4 are considered out of phase because they do not occur simultaneously.

Regarding claim 14, any system designed and manufactured to produce a certain polarity of pulse can be said to have polarities determined according to a "polar profile." The "polar profile" can simply relate to a pulse design criteria established by the profiler (i.e., circuit designer) prior to construction of the invention.

Regarding claim 15, Kallok has selected a sequence of four pulses.

Regarding claims 22 and 23, Kallok teaches that the frequency (i.e., pulse rate) of output pulses may be adjusted either manually or automatically (note col. 2, lines 13-24). A user interface would inherently be required to allow for such adjustment.

Regarding claim 24, an implantable unit is inherently configured for attachment to a user.

Regarding claim 25, whether the user interface fits within a pocket of the wearer simply depends upon how big the pocket is. The pocket is a non-element of the invention. The examiner considers any implantable device (and even more so a subunit of the device such as a user interface which may simply relate to a telemetry coil or a set of sensing electrodes, etc.) to be configured for fitting within a pocket.

Regarding claim 26, since the applicant has chosen not to invoke the 6th paragraph of §112, the examiner is free to interpret the term "user interface" and "diagnostic equipment" in its broadest reasonable sense and is not limited to embodiments disclosed by the applicant and equivalents thereof. In this case, the examiner considers the user interface to be the sensing electrodes that interface to the body and enable the frequency of output pulses to be automatically adjusted. The electrodes are considered to be diagnostic equipment. Other interpretations are possible due to the broadness of the claim.

Comments related to those above apply to substantially similar apparatus claims 31, 33, 35, 36, 38, 41-43, 47 and 49-56.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 20, 48, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallok.

Concerning claims 20 and 48, Kallok does not disclose generating a sequence wherein successive pulses have a shorter width than preceding pulses. The phenomena of muscle fatigue is, however, widely known by those of ordinary skill in the art, along with stimulation techniques to combat such fatigue. The examiner took Official Notice in the previous Office Action that it was old and well-known to reduce muscle adaptation resultant from stimulation by modifying parameters of the stimulation pulse such as width, frequency, amplitude, etc. To alter the pulse width from one pulse to the next so as to provide a varied signal would have been considered a matter of obvious design by those of ordinary skill in the stimulator arts.

With respect to claims 58 and 59, while Kallok does not explicitly refer to the use of a program product, the examiner does not consider the product to be patentably distinct from the method and apparatus as evidenced by the restriction requirement grouping the three inventions together. In any event, those of ordinary skill in the electronics arts would have seen the provision of a memory device containing programming code to control operation of the implantable medical device set forth by Kallok to be a matter of obvious design. Official Notice was taken in the previous Office Action that the use of programs stored on recordable and "transmission-type" media to control medical devices is old and well-known in the art.

5. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallok in view of Schulman et al. (Pat. No. 5,193,539).

Regarding claims 17 and 45, Kallok does not recite the use of charge-balanced pulses. Schulman et al., however, teach that charge-balanced pulses help to prevent damage to body tissues from constant application of currents in one direction. Given that the use of such pulses are old and well-known in the medical stimulator arts, and given the universal teaching that damage can be prevented in body tissues by using such pulses, those of ordinary skill in the art desiring to prevent muscle damage would have seen the obviousness of employing charge-balanced pulses in the system of Kallok.

Response to Arguments

6. Applicant's arguments filed February 24, 2005 have been fully considered but they are not persuasive.

Addressing the applicant's argument that the Kallok reference teaches away from uniformly initiating a contraction as is now set forth in claim 1, the examiner responds that the functional language "...to uniformly initiate a contraction within the musculature..." is merely a statement of desired result that the applicant wishes to obtain by a performance of the recited steps. Kallok's resonant sequence of pulses are spaced relative to one another and, as previously discussed, effectively progressively stimulate and create tension in the musculature while maintaining the tension created in at least a portion of the musculature by each preceding pulse in the sequence (see Figs. 1a-1c), albeit for the purpose of preventing a fused tetanic contraction. The reason for performing a step or steps, however, cannot be relied upon to distinguish over the prior art --only the actual steps themselves can be relied upon to differentiate one method over the other. By analogy, a claim directed to a method of baking comprising the step of turning on the oven *to bake a cake*, would not distinguish over a prior art reference disclosing a method of baking comprising the step of turning on an oven *to bake bread* (an additional step of placing a pan of cake batter in the oven would, however, likely distinguish between the two). Thus, whether one performs the recited steps to create a contraction or performs the recited steps to prevent a

Art Unit: 3762

contraction, is immaterial to the method in the absence of any step specifically precluding one result over the other.

The examiner will, however, agree with the applicant that claims 9 and 39 are not obvious in view of the Kallok reference. Kallok teaches in col. 2, lines 1-10 to apply pulses at a frequency that is too slow to allow a fused tetanic contraction. The present invention's recitation of pulses separated by a spacing of around 3 to 10 microseconds would therefore appear to be too fast with respect to the frequencies typically employed by Kallok.

In the previous Office Action, the examiner took Official Notice that the limitations presented in claims 20, 48, 58 and 59 were old and well-known. As the applicant has failed to address this issue, the statement of common knowledge is now admitted prior art.

The rejection of claims 17 and 45 in view of the combination of Kallok and Schulman is maintained for the same reasons given above in the rejection of claims in view of Kallok.

Allowable Subject Matter

7. Claims 9 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

See the comments pertaining to claims 9 and 39 above.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3762

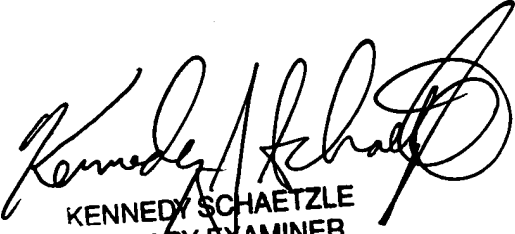
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 13, 2005



KENNEDY SCHAETZLE
PRIMARY EXAMINER